UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No. SA CV 15-1859 (DFMx) Date: August 30, 2016

Title: DUANE ROBERT GREENE, ET AL. V. FIVE PAWNS, INC.

PRESENT:

THE HONORABLE DAVID O. CARTER, JUDGE

Deborah Goltz	Not Present
Courtroom Clerk	Court Reporter
ATTORNEYS PRESENT FOR PLAINTIFF: None Present	ATTORNEYS PRESENT FOR DEFENDANT: None Present

PROCEEDINGS (IN CHAMBERS): ORDER GRANTING IN PART MOTION TO DISMISS SECOND AMENDED COMPLAINT [31]

Before the Court is Defendant Five Pawns, Inc.'s ("Five Pawns" or "Defendant") Motion to Dismiss Second Amended Complaint ("Motion") (Dkt. 31). The Court finds this matter appropriate for resolution without oral argument. Fed. R. Civ. P. 78; L.R. 7-15. Having reviewed the papers and considered the parties' arguments, the Court hereby GRANTS Defendant's Motion IN PART.

I. Background

Plaintiffs filed suit on November 11, 2015. *See generally* Complaint ("Compl.") (Dkt. 1).

On April 18, 2016, the Court granted in part Five Pawns' motion to dismiss the First Amended Complaint ("FAC Order") (Dkt. 27). The Court adopts by reference the factual history from the FAC Order, except where altered by this Order.

Plaintiffs filed their Second Amended Complaint on May 9, 2016 ("SAC") (Dkt. 28). Plaintiffs allege: (1) violations of the Consumers Legal Remedies Act, California

Civil Code §§ 1750, *et seq*. ("CLRA"), (2) violations of the unfair competition law under California Business & Professions Code §§ 17200, *et seq*. ("UCL"), (3) violations of the false advertising law under California Business & Professions Code §§ 17500, *et seq*. ("FAL"), (4) breach of the Indiana Deceptive Consumer Sales Act, Indiana Code § 24-5-0.5, *et seq*. ("IDCSA"), (5) violations of the New York General Business Law § 349 ("GBL"), and (6) violations of the Vermont Consumer [Fraud] Act, 9 V.S.A. § 2451a, *et seq*. ("VCFA"). [1]

Defendant filed the instant Motion on June 8, 2016, moving to dismiss Plaintiffs' claims under Rule 12(b)(1) and Rule 12(b)(6) on the grounds of express preemption, implied preemption and primary jurisdiction. Plaintiffs opposed on July 8, 2016 (Dkt. 32), and Defendant replied on July 25, 2016 (Dkt. 33).

II. Defendant's Request for Judicial Notice

Defendant asks the Court to take judicial notice of four documents: (1) the Food and Drug Administration's ("FDA") recently finalized rule entitled "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" ("ENDS Regulations");[2] (2) draft guidance from the FDA issued in 2016 entitled "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems" ("Draft Guidance"); the fourth consolidated amended complaint from *In re NJOY, Inc. Consumer Class Action Litigation*, 120 F. Supp. 3d 1050 (C.D. Cal. 2015) ; and the complaint in *Cox v. Cutwood, LLC*, Case No. 30-2016-838588-CU-BC-CXC. Request for Judicial Notice (Dkt. 31-3).

Pursuant to Federal Rule of Evidence 201, "[a] court shall take judicial notice if requested by a party and supplied with the necessary information." Fed. R. Evid. 201(d). An adjudicative fact may be judicially noticed if it is "not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Thus, a court "may take judicial notice of matters of public record, including duly recorded documents, and court records available to the public through the Pacer system via the internet." *C.B. v. Sonora Sch. Dist.*, 691 F. Supp. 2d 1123, 1138 (E.D. Cal. 2009); *see also Holder v. Holder*, 305 F.3d

[1] Plaintiffs refer to the Vermont Consumer Fraud Act as the Vermont Consumer Protection Act. However, the Court follows courts in the District of Vermont, which refer to 9 V.S.A. § 2451a, *et seq*. as the Vermont Consumer Fraud Act. *See, e.g.*, *Bergman v. Spruce Peak Realty, LLC*, 847 F. Supp. 2d 653, 671 (D. Vt. 2012).

[2] The Court notes that the ENDS Regulations were located at 81 Fed. Reg. at 28974 and have now been placed into the Code of Federal Regulations at 21 C.F.R. § 1100 *et. seq.*

854, 866 (9th Cir. 2002). The contents of the Federal Register are noticeable as a matter of law. *See* 44 U.S.C. § 1507 ("The contents of the Federal Register shall be judicially noticed . . . ."). The Court can also take judicial of the pleadings, although it cannot take judicial notice of findings of facts from another case. *Walker v. Woodford*, 454 F. Supp. 2d 1007, 1022 (S.D. Cal. 2006), *aff'd in part*, 393 Fed. Appx. 513 (9th Cir. 2010). The Court may also take judicial notice of documents available on a government agency's website. *Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1113 n.1 (N.D. Cal. 2013).

Plaintiffs have not objected to the request for judicial notice. The Court finds all four documents are appropriate subjects of judicial notice and accordingly the Court GRANTS Defendant's Request for Judicial Notice.

III. Motion to Dismiss under Rule 12(b)(1)

A. Legal Standard

Dismissal is appropriate under Federal Rule of Civil Procedure 12(b)(1) when a court lacks subject matter jurisdiction due to a plaintiff's lack of Article III standing. *White v. Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000); *see Maya v. Centex Corp.*, 658 F.3d 1060, 1067 (9th Cir. 2011) (stating Article III standing bears on the court's subject matter jurisdiction, and is therefore subject to challenge under Federal Rule of Civil Procedure 12(b)(1)).

The "irreducible constitutional minimum" of Article III standing has three elements. First, the plaintiff must have suffered an "injury in fact" – an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *see also Townley v. Miller*, 722 F.3d 1128, 1133 (9th Cir. 2013). Second, there must be a causal connection between the injury and the conduct complained of – the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court. *Lujan*, 504 U.S. at 560. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *Id.* The plaintiff, as the party invoking federal jurisdiction, has the burden of establishing these elements. *See id.* at 561. In reviewing such a motion, courts must take the allegations in the plaintiff's complaint as true and draw "all reasonable inferences in [plaintiff's] favor." *Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004).

B. Discussion

In the FAC Order, the Court dismissed without prejudice Plaintiffs' claim for injunctive relief because they had not sufficiently alleged that they intended to purchase the product in the future and thus did not have standing under Article III to seek prospective relief. FAC Order at 14. Plaintiffs have since amended their complaint and now contend they have cured the deficiency identified by the Court in the FAC Order. Opp'n at 4. The relevant allegations in the SAC now state:

> In the future, if Defendant were to disclose the presence in its products of DA and AP and their related health risks, Plaintiffs would be in a position to make an informed decision as to whether to purchase Defendant's products at the prices offered.

SAC ¶ 26. Virtually identical language is used for each of the five named Plaintiffs. *See* SAC ¶¶ 27–31. The SAC also alleges "Plaintiffs would be interested in purchasing Defendant's products in the future" if Defendant made proper disclosures which would put Plaintiffs in a position to determine whether or not to purchase the products at that price. *Id.* ¶ 113.

In the FAC Order, the Court identified three different approaches that have been taken by other district courts in determining whether a plaintiff has sufficiently pleaded standing to seek injunctive relief. FAC Order at 12–13. During the previous round of briefing, Plaintiffs argued the Court should follow the first group of cases, which created a type of "policy exception" that permitted plaintiffs to pursue injunctive relief even when they had no intent on purchasing the product in the future. *Id.* at 12. However, the Court followed the third group of cases, holding that where the plaintiffs have expressed no interest in purchasing the product in the future, they lack a real and immediate threat of future injury. *Id.* at 13. Plaintiffs assert that the new language in the SAC is sufficient to show that there is a real and immediate threat of harm, Opp'n at 4, while Defendant argues that because the alleged injury involves multiple layers of doubt it is too remote to satisfy Article III, Reply at 24–25.

In the FAC Order, the Court indicated it was following the reasoning of cases like *Mason v. Nature's Innovation, Inc.*, Case No. 12-cv- 3019, 2013 WL 1969957 at *4–5 (S.D. Cal. May 13, 2013). The *Mason* court, in dicta, stated that plaintiffs would need to allege that they were still interested in purchasing the product, which was impossible because the plaintiff had alleged the product did not work. *Id.* at 5. This is similar to other cases where plaintiffs sought prospective relief against products that did not work, or where plaintiffs have argued they did not need to allege an interest in purchasing the

product. *See, e.g*, *Delarosa v. Boiron, Inc.*, No. SACV 10-1569-JST CWX, 2012 WL 8716658, at *4 (C.D. Cal. Dec. 28, 2012) (holding that a plaintiff who testified the homeopathic product did not work and who did not dispute that she does not intend to purchase the product does not have standing for injunctive relief); *Jou v. Kimberly–Clark Corp.*, No. 13-cv-3075, 2013 U.S. Dist. LEXIS 173216, at *13 (N.D. Cal. Dec. 10, 2013) (rejecting "Plaintiffs' contention that it is unnecessary for them to maintain any interest in purchasing the products in the future" in order to establish Article III standing for injunctive relief); *Forcellati v. Hyland's, Inc.*, No. CV 12-1983-GHK MRWX, 2014 WL 1410264, at *12–13 (C.D. Cal. Apr. 9, 2014) (holding that a plaintiff who purchased a homeopathic product that did not work and who also argued that the Article III standing requirement did not apply in consumer protection cases lacked standing to pursue injunctive relief).

Defendant argues that because Plaintiffs have conditioned their future purchasing on Defendant disclosing the chemicals in the product, Reply at 25, and the relative price, Reply at 5, Plaintiffs' intent is several layers removed from Article III standing. Reply at 25. The Court is not persuaded that Plaintiffs' concern over price and proper disclosure makes their interest too remote or unlikely. Defendant has not identified any particular facts about Plaintiffs' price sensitivity that would tend to show that Plaintiffs are less likely to buy the products at their current or future price.

Plaintiffs are all people who purchased multiple bottles of Defendant's e-liquids in the past, SAC ¶¶ 27–31, Defendant's e-liquids contain nicotine, SAC ¶ 8, nicotine is addictive and habit forming, SAC ¶ 65, and Plaintiffs are interested in buying the product if they can rely on its labeling, SAC ¶ 113. Drawing all reasonable inferences in Plaintiffs' favor, *Wolfe*, 392 F.3d at 362, the Court concludes Plaintiffs have demonstrated sufficient likelihood they will be wronged again in a similar way. *See City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983).

Defendant is also incorrect in arguing that the Court rejected the reasoning of *Ries v. Arizona Beverages USA LLC*, 287 F.R.D. 523, 533 (N.D. Cal. 2012), and therefore also rejected the reasoning in *Lilly v. Jamba Juice Co.*, Case No. 13-cv-02999-JST, 2015 U.S. Dist. LEXIS 34498 (N.D. Cal. Mar. 18, 2015). The *Ries* court articulated a type of "policy exception" that this Court rejected. FAC Order at 12. However, the portion of the decision addressing the "policy exception" appears to have been dicta as the plaintiff provided undisputed evidence that she intended to purchase the product in the future. *Ries*, 287 F.R.D. at 533. This is why *Ries* has been cited with approval by the third category of cases. *See, e.g. Mason*, 2013 WL 1969957 at *4; *Delarosa*, 2012 WL 8716658, at *5. The Court therefore takes no position on the applicability of the reasoning in *Lilly v. Jamba Juice Co.*, 2015 U.S. Dist. LEXIS 34498.

Based on the foregoing, the Court DENIES Defendant's Motion to Dismiss Plaintiffs' claims for injunctive relief based on a lack of standing.

IV. Motion to Dismiss under Rule 12(b)(6)

A. Legal Standard

Under Federal Rule of Civil Procedure 12(b)(6), a complaint must be dismissed when a plaintiff's allegations fail to set forth a set of facts that, if true, would entitle the complainant to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (holding that a claim must be facially plausible in order to survive a motion to dismiss). The pleadings must raise the right to relief beyond the speculative level; a plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). On a motion to dismiss, the court accepts as true a plaintiff's well-pleaded factual allegations and construes all factual inferences in the light most favorable to the plaintiff. *See Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). However, the court is not required to accept as true legal conclusions couched as factual allegations. *Iqbal*, 556 U.S. at 678.

For claims sounding in fraud, a complaint must be dismissed when a plaintiff fails to meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009); *see* Fed. R. Civ. P. 9(b). Rule 9(b) requires a plaintiff alleging such claims to "state with particularity the circumstances constituting fraud." *Id.* The "circumstances" required by Rule 9(b) are the "who, what, when, where, and how" of the fraudulent activity. *United States ex rel Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011). Further, if the plaintiff claims a statement is false or misleading, "[t]he plaintiff must set forth what is false or misleading about a statement, and why it is false." *Vess v. Ciba–Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (quoting *In re Glenfed, Inc. Secs. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994)). In other words, the plaintiff "must set forth an explanation as to why the statement or omission complained of was false or misleading." *Cooper v. Pickett*, 137 F.3d 616, 625 (9th Cir. 1997). This heightened pleading standard ensures that "allegations of fraud are specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir. 1985). However, "intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); *see Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993).

Although review of a motion to dismiss is ordinarily limited to the contents of the complaint and material properly submitted with the complaint, *Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002), the court may also consider documents "whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the pleading." *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994), *overruled on other grounds by Gilbraith v. Cty. of Santa Clara*, 307 F.3d 1119, 1121 (9th Cir. 2002). This includes "internet pages as it does . . . printed material." *In re iPhone 4S Consumer Litigation*, Case No. 12-cv-1127, 2013 WL 3829653, at *6 (N.D. Cal. July 23, 2013) (citing *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005)). The court may treat such referenced documents as "part of the complaint, and thus may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6)." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003).

In granting a motion to dismiss, dismissal with leave to amend should be freely given "when justice so requires." Fed. R. Civ. P. 15(a)(2). This policy is applied with "extreme liberality." *Morongo Band of Mission Indians v. Rose*, 893 F.2d 1074, 1079 (9th Cir. 1990); *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (holding that dismissal with leave to amend should be granted even if no request to amend was made). Dismissal without leave to amend is appropriate when the court is satisfied that the deficiencies in the complaint could not possibly be cured by amendment. *Jackson v. Carey*, 353 F.3d 750, 758 (9th Cir. 2003).

B. Waiver under Rule 12(g)(2)

"Federal Rule of Civil Procedure 12(g)(2) states that '[e]xcept as provided in Rule 12(h)(2) or (3), a party that makes a motion under this rule must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion.' Federal Rule of Civil Procedure 12(h)(2), in turn, provides that arguments which pertain to a plaintiff's '[f]ailure to state a claim upon which relief can be granted . . . may be raised: (A) in any pleading allowed or ordered under Rule 7(a); (B) by a motion under Rule 12(c); or (C) at trial.' To summarize, under Rule 12(g)(2) and Rule 12(h)(2), a party that seeks to assert a defense that was available but omitted from an earlier Rule 12 motion can only do so in a pleading, a Rule 12(c) motion, or at trial." *In re Anthem, Inc. Data Breach Litig.*, No. 15-MD-02617-LHK, 2016 WL 3029783, at *44 (N.D. Cal. May 27, 2016).

In its first Rule 12 motion, Defendant did not raise any preemption arguments. *See generally* Motion to Dismiss First Amended Complaint (Dkt. 22). Plaintiffs therefore argue that Defendant has waived new grounds for asserting that the SAC fails to state a claim unless done in a manner that complies with Rule 12(g)(2). Plaintiffs argue that

defenses based on preemption and primary jurisdiction were fully available to Defendant when it filed its first motion to dismiss. Opp'n 4. The relevant statute for the preemption analysis is the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, June 22, 2009, 123 Stat 1776 ("TCA"). The TCA was enacted in 2009 as Subchapter IX of the Food, Drug, and Cosmetic Act ("FDCA"), and is codified at 21 U.S.C. §§ 387–387u. For reasons explained below, the TCA did not apply to Defendant's products until May 2016, after the Court ruled on Defendant's first Rule 12 motion. Thus, a preemption defense based on the text of the TCA was not available when Defendant filed its first Rule 12 motion, so Defendant has not waived the preemption defense.

In contrast, the defense of primary jurisdiction was fully available to Defendant when it filed its first Rule 12 motion. However, primary jurisdiction can be raised by the court *sua sponte*, even on appeal, suggesting it cannot be waived. *See Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 n.2 (9th Cir. 2002). For this reason the Court finds that Defendant has not waived its primary jurisdiction argument.

C. Preemption

Defendant contends that Plaintiffs' claims should be dismissed because they are expressly and impliedly preempted under the TCA. Mot. at 10–15.

1. Legal Framework

Preemption is fundamentally a question of Congressional intent. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). "Federal preemption occurs when: (1) Congress enacts a statute that explicitly pre-empts state law; (2) state law actually conflicts with federal law; or (3) federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field." *Chae v. SLM Corp.*, 593 F.3d 936, 941 (9th Cir.2010) (citation and internal quotation marks omitted).

Two presumptions regarding preemption guide the courts. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). First, courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress" because "the States are independent sovereigns in our federal system;" in other words, there is a starting presumption "that Congress does not cavalierly pre-empt state-law causes of action." *Id.*; *see Wyeth*, 555 U.S. at 565. This assumption is heightened where a state or locality seeks to exercise its police powers to protect the health and safety of its citizens. *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 432–33 (2d Cir. 2013). Accordingly, if there is any ambiguity as to whether the local and federal laws can coexist, the Court must uphold the

ordinance. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) Second, the "ultimate touchstone" in every preemption case is Congressional purpose and intent. *Medtronic*, 518 U.S. at 485. "Congressional intent to preempt state law must be clear and manifest." *Indus. Truck Ass'n, Inc. v. Henry*, 125 F.3d 1305, 1309 (9th Cir.1997); *see United States v. Locke*, 529 U.S. 89, 108 (2000).

"Parties seeking to invalidate a state law based on preemption 'bear the considerable burden of overcoming the starting presumption that Congress does not intend to supplant state law.'" *Stengel v. Medtronic*, 704 F.3d 1224, 1227–28 (9th Cir. 2013) (en banc) (quoting *De Buono v. NYSA–ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814, (1997)). Moreover, a defendant asserting preemption bears the burden of proving that it applies. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 251 n.2 (2011) ("Federal preemption is an affirmative defense upon which the defendants bear the burden of proof.") (citations omitted).

Defendant does not argue that the TCA preempts the field of regulation, but rather that express or other types of implied preemption apply. The Court will address these arguments in turn.

2. Express Preemption

Express preemption results from a Congressional expression of intent to displace state law. *Chae*, 593 F.3d at 942. Where Congress enacts an express preemption provision, a court must interpret the provision and "identify the domain expressly pre-empted by that language" based upon the text of the provision, the statutory framework, and any Congressional statement of its purposes in enacting the provision. *Medtronic*, 518 U.S. at 484 (internal quotation marks omitted).

The TCA contains an elaborate preemption scheme. 21 U.S.C. § 387p. In particular, it contains a broad preservation clause that preserves the authority of federal agencies, states, local governments, and Indian tribes to regulate virtually any aspect of tobacco products, regardless of the regulations promulgated under the TCA or even the text of the TCA, except for what is covered by the TCA's preemption provision. 21 U.S.C. § 387p(a)(1). The preemption provision states:

> No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards,

> premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

21 U.S.C.A. § 387p(a)(2)(A). This provision is followed by the saving clause, which states:

> Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of Title 5 shall be treated as a trade secret and confidential information by the State.

21 U.S.C. § 387p(a)(2)(B). The section also expressly exempts state product liability laws from preemption. 21 U.S.C. § 387p(b) ("No provision of this subchapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.").

Thus, by its plain text, the preemption provision only applies to a state requirement that is different from or in addition to the misbranding, labeling, and premarket review provisions of the TCA. *Cf. Medtronic*, 518 U.S. at 488 (stating that the Medical Device Amendments, 21 U.S.C. § 360k, preempted state laws that imposed a requirement that was different from or in addition to the requirements imposed by that statute).

The TCA also amended the FDCA to define tobacco products as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr) (as amended by the TCA). Congress, however, expressly limited the applicability of the TCA to "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b). The recently finalized ENDS Regulations deemed all products within the FDCA's definition of tobacco product to fall under the requirements of the TCA. 21 C.F.R. § 1100.1. Thus, in order for the TCA to expressly preempt Plaintiffs' claims, Defendant must establish that its products fall under the definition of a tobacco product, and that Plaintiffs' claims are covered by the preemption provision. The burden then shifts to Plaintiffs to show the claim is

preserved by the saving clause or by the products liability provision. *See Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1288 (C.D. Cal. 2008).

Defendant fails to establish its products are tobacco products, nor does the SAC allege that the products are tobacco products. The SAC, however, does allege the products are e-liquids, SAC ¶ 2, that contain nicotine, *id.* ¶ 8, and the Court has taken judicial notice of the ENDS Regulations, which state that e-liquids with nicotine are a component and part of tobacco products and covered under the new regulation. ENDS Regulations at 28,975, 29017.[3] The Court therefore finds that the products described in the SAC are tobacco products within the meaning of the TCA.

Next, Defendant must show that the requirements that Plaintiffs seek to impose are expressly preempted by the TCA. Defendant argues that Plaintiffs' claims are preempted by the misbranding, Mot. at 11, labeling, *id* at 13, and premarket review, *id.* at 14, clauses of the preemption provision. The Court will address these arguments in turn.

a. Misbranding

The TCA contains a section on misbranded tobacco products, 21 U.S.C. § 387c, which applies to all newly deemed products. 81 Fed. Reg. at 29,051. 21 U.S.C. § 387c(a)(1) states that a product will be deemed misbranded if its labeling is "false or misleading in any particular." The TCA does not define labeling, but subchapter II of the FDCA is titled "Definitions" and includes definitions for labeling, 21 U.S.C. § 321(m), and label, § 321(k). Labeling is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). Label is defined in relevant part as "a display of written, printed or graphic matter upon the immediate container of any article." *Id.* § 321(k). Plaintiffs' allegations in the SAC center around false or misleading statements made by Defendant that were conveyed on the packaging, packing inserts and shipping materials, and Defendant's website. SAC ¶ 60.

Plaintiffs cite two cases, *Cortina v. Goya Foods Inc.*, 94 F. Supp. 3d 1174 (S.D. Cal. 2015) and *Sciortino v. Pepsico, Inc.*, 108 F. Supp. 3d 760 (N.D. Cal. 2015), to argue that other courts interpreting similar language in other parts of the FDCA have held that state causes of action based upon omissions have not been preempted. Opp'n at 11–12. Both cases concern the presence of a known carcinogen, 4-methylimidazole, that was added to beverages. *Cortina*, 108 F. Supp. 3d at 1180; *Sciortino*, 108 F. Supp. 3d 786.

[3]The Court takes no position on whether e-liquids without nicotine meet the definition of tobacco products.

The preemption provisions in those cases, however, related to food colorings, and did not preempt issues relating to carcinogens. *See, e.g.*, *Cortina*, 108 F. Supp. 1187–87.

Defendant however has not shown that the state requirements Plaintiffs seek to impose are additional to or different from the federal requirements for misbranding. Particularly useful for this analysis is the Ninth Circuit case *Astiana v. Hain Celestial Group*, 783 F.3d 753, 757–59 (9th Cir. 2015). The case concerned cosmetic products that were labeled "All Natural," "Pure Natural," or "Pure, Natural & Organic," but contained artificial ingredients that were disclosed on the FDA-mandated label. *Id.* at 756, 758. The FDCA deemed a cosmetic to be misbranded "[i]f its labeling is false or misleading in any particular[,]" identical language to the TCA. 21 U.S.C. § 362(a). The FDCA also preempted "any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is not otherwise identical with" federal rules. *Id.* § 379s(a). This preemption provision is actually broader than the TCA because it covers all of the requirements of the FDCA that apply to cosmetics, while the TCA only expressly preempts specific sections. *Compare id.* with *id* § 387p(a)(2)(A). The defendant cosmetic company argued that finding against preemption would allow state law to create a "novel state labeling requirement," and that the FDA had never issued specific regulations on use of the word 'natural,' which was tantamount to a conscious decision to permit manufacturers to use the word as they saw fit. *Astiana*, 783 F.3d at 757–58.

The Ninth Circuit disagreed on both points. *Id.* First, the panel held that as long as the consumers were not seeking liability based on the FDA-mandated label and were not asking the company to modify or enhance any aspect of its labels required by federal law, the suit was not necessarily preempted. *Id.* at 758. Second, the Ninth Circuit held that the FDCA proscribing statements that were "false or misleading in any particular" did not mean only statements that were "prohibited by specific FDA regulations." *Id.* Finally, following the Supreme Court's instructions in *Bates*, 544 U.S. at 452, the panel held that the appropriate way to deal with the FDCA's preemption of different, additional, and non-identical requirements was not to dismiss the suit, but to instruct the jury on the relevant federal standards and regulations. *Astiana*, 783 F.3d at 757–58.

Astiana is relevant to the misbranding question here. Defendant has made virtually identical arguments to those made by the cosmetics company and rejected by the Ninth Circuit. Defendant argues Plaintiffs are seeking to impose a novel state law theory of disclosure, and because the FDA has not required disclosure of AP and DA, its labeling cannot be misleading. Mot. at 12. The Court therefore rejects both of these arguments and, following *Astiana*, 783 F.3d at 757–59, finds Plaintiffs' state law claims are preempted to the degree that they impose labeling requirements that are additional to or different from the federal standard for false or misleading tobacco products under the

TCA. 321 U.S.C. § 387c. The solution however, is to instruct the jury on the relevant federal standard. *Bates*, 544 U.S. at 453–54; *Astiana*, 783 F.3d at 757–58.

Because 21 U.S.C. § 387c only applies to misbranding on labeling, the Court must determine what constitutes labeling. Mot. at 14. The FDCA's definition of labeling, 21 U.S.C. § 321(m), only applies to written, printed, or graphic material that accompanies an article. The Court agrees that the label on the bottle, its packaging, and the packaging insert that accompany the e-liquids bottle constitute labeling under the FDCA, but Defendant has not explained how a website accompanies a bottle of e-liquid, particularly when Plaintiffs reference statements in the "News" section, SAC ¶¶ 69–70, and in blog posts, SAC ¶¶ 77, 83. The Court therefore finds the statements on Defendant's website that Plaintiffs reference in the SAC do not constitute labeling within the FDCA's definition.

Accordingly, Defendant's Motion to dismiss is GRANTED IN PART. Claims based on the labeling are preempted to the degree they are different from or in addition to the federal misbranding requirements, but claims based on Defendant's website are not preempted.

b. Labeling

Under 21 U.S.C. § 387p(a)(2)(A) state law requirements are expressly prempted that are in addition to or different from the TCA's provisions relating to labeling. Defendant argues for an expansive definition of the term, citing to the FDCA's definition of labeling, 21 U.S.C. § 321(m), and *American Meat Institute. v. Leeman*, 180 Cal. App. 4th 728 (Cal. Ct. App. 2009), which summarized *Kordel v. United States*, 335 U.S. 345 (1948) (interpreting 21 U.S.C. § 321(m)). Mot. at 13–14. This argument, however, ignores the actual text of the preemption provision that Defendant attempts to enforce. The preemption provision states:

> No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

21 U.S.C. § 387p(a)(2)(A). Every topic after "relating to" is the title of a specific section or subsection of the TCA. § 387g (Tobacco Product Standards); § 387j(a)(2) (Premarket Review); § 387b (Adulterated Tobacco Products); § 387c (Misbranded Tobacco

Products); § 387t(a) (Origin Labeling); § 387e (Annual Registration); § 387f(e) (Good Manufacturing Standards); § 387k (Modified Risk Tobacco Products). This shows Congress' intent to give express preemptive force only to specific sections and subsections of the TCA, and demonstrates that Congress' use of the word "labeling" in 21 U.S.C. § 387p(a)(2)(A) does not mean the ordinary sense of the word or the FDCA's definition, but rather the TCA subsection entitled "Origin Labeling." *Id.* § 387t(a). As used in that section, labeling refers to the origin labeling requirement in the TCA that requires the label, packaging, and shipping containers of tobacco products, including Defendant's, to state "sale only allowed in the United States." *Id.* § 387t(a).

Accordingly, Defendant's motion to dismiss Plaintiffs' claims on this basis is DENIED.

c. Premarket Review

Defendant's final express preemption argument is that Plaintiffs' claims are expressly preempted by the premarket review provision of the TCA. Mot. at 14–5. The premarket review provision of the TCA, 21 U.S.C. § 387j(a)(2), requires a new tobacco product to submit a premarket tobacco application ("PMTA") unless the product is substantially equivalent to a grandfathered product, § 387j(a)(2)(i), or the product receives an exemption, § 387j(a)(2)(ii).

Defendant argues that if Plaintiffs prevail and the Court orders disclosure of the AP and DA chemicals, Defendant would be required to remove certain products from the market, and injunctive relief would impose a requirement that is in addition to or different from the premarket review requirements, which do not require corrective action. Mot. at 15. Defendant provides no explanation for why it would have to remove products from the market if it were forced to disclose the presence of AP and DA. Plaintiffs have not asked for an injunction prohibiting the sale of Defendant's products, nor has Defendant explained how this is connected to the premarket review process. Defendant also does not explain how the premarket review process preempts a state law disclosure requirement. SAC ¶ 60. Defendant does not even establish that it would be subject to a premarket review, given the alternative pathways in 21 U.S.C. §§ 387j (a)(2)(i)–(ii). The burden of showing preemption is on Defendant, *Stengel*, 704 F.3d at 1227–28, and there are no facts in the record that would permit the Court to determine whether Defendant's products are substantially similar to a potentially grandfathered product. Most importantly however, Defendant never appears to cite to any section of § 387j or the final rule, 21 C.F.R § 1100 *et. seq.*, making it impossible to determine what part of Plaintiffs' claims Defendant contends is expressly preempted by the premarket review process.

Based on the foregoing, Defendant's motion to dismiss Plaintiffs' claims on this basis is DENIED.

2. Implied Preemption

a. Implied Preemption under 21 U.S.C. § 337(a)

Defendant next argues that Plaintiffs' claims are impliedly preempted because all actions to enforce the FDCA "shall be by and in the name of the United States," 21 U.S.C. § 337(a). Reply at 15. Defendant does not explain how Plaintiffs are attempting to enforce the FDCA, especially because, as explained above, this suit was filed before the FDCA applied to Defendant's products. *See* Reply at 6.

The argument Defendant makes here is frequently asserted by defendants in food labeling cases brought pursuant to the UCL, CLRA and FAL, and is routinely rejected by the courts. *See Vassigh v. Bai Brands LLC*, No. 14-CV-05127-HSG, 2015 WL 4238886, at *4 (N.D. Cal. July 13, 2015) (collecting cases). Defendant argues that there is only a "narrow gap" through which Plaintiffs' claims can fit to avoid the express preemption provisions (presumably 21 U.S.C. § 387p) and implied preemption in 21 U.S.C. § 337(a). Reply at 15. For support, Defendant cites *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015), but that case, like the Ninth Circuit precedent in *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013), analyzed the express preemption provision in the Medical Device Amendments, 21 U.S.C. § 360k, which is significantly broader than 21 U.S.C. § 387p and does not include a preservation clause or saving clause. The differences in the preemption provisions show that the "gap" for tobacco products under the TCA is much larger than the gap for medical devices.

In addition to the above reasons, because Plaintiffs are pursuing claims based on violations of state law and not claims based solely on a violation of federal law, the claims are not attempting to enforce the FDCA and are not preempted by 21 U.S.C. § 337(a). *Perez*, 711 F.3d at 1119–20.

Accordingly, Defendant's motion to dismiss Plaintiffs' claims on this basis is DENIED.

b. Conflict Preemption

Conflict preemption arises when "compliance with both federal and state regulations is a physical impossibility." *Bank of America v. City and County of San Francisco*, 309 F.3d 551, 558 (9th Cir. 2002) (citing *Florida Lime & Avocado Growers Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)). Conflict preemption may also exist where

"state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

A significant obstacle occurs when state laws "prevent or frustrate the accomplishment of a federal objective." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000). "A state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach this goal." *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987). Showing conflict preemption, *i.e.* preemption by impossibility, is a "demanding defense." *Wyeth*, 555 U.S. at 573.

Plaintiffs argue that because the FDA took no action regarding AP and DA there is no conflict to preempt. Opp'n at 11. Plaintiffs also argue that not only has Defendant failed to explain how disclosing the presence of AP and DA would obstruct nicotine labeling, such a requirement would actually further the FDA's goal of bolstering consumer protection against harmful products. *Id.* at 12–3.

Defendant bears the considerable burden of overcoming the presumption that a state law is not conflict preempted. *Stengel*, 704 F.3d at 1227. Defendant has failed to meet that burden because it misunderstands critical aspects of the ENDS Regulations and also makes arguments that are inappropriate on a motion to dismiss. Both parties agree that the FDA did not require labels like Defendant's to disclose the presence of AP or DA. Mot. at 17; Reply at 12. And neither party alleges the FDA has prohibited Defendant from disclosing AP and DA. Defendant instead argues in the abstract that state disclosure laws could interfere with the FDA's nicotine disclosures by requiring Defendant to disclose the presence and health risk of every potentially harmful constituent. Reply at 18. This argument is not supported by anything in the record showing a lack of label space. It is also not applicable because Plaintiffs are not asking for every product to be disclosed, only AP and DA, SAC ¶ 8, and it would not apply to Plaintiffs' claims that Defendant's advertising was misleading ¶ 60. Defendant's argument would only apply if its products contain so many potentially harmful constituents that it could not fit them on the label. Defendant's argument about "over warning" is similarly inapplicable at this stage because Defendant has not pointed to any evidence that including a warning about potential harms from AP and DA could crowd out more important warnings or mislead consumers.

Defendant's arguments relating to the compliance period, Mot. at 18, and the FDA's "meticulous consideration of scientific evidence," *id.* at 17, both misread the ENDS Regulations. Defendant appears to treat the compliance period as if it conveyed a substantive right to be free of all regulations during the period. Reply at 2 (arguing that Plaintiffs' requested injunction would be in direct contravention to the compliance

policy). The compliance policy, however, does not have the force of law because it is an interpretive rule. 81 Fed. Reg. at 28,977 (identifying the compliance as not subject to notice and comment, and distinct from the final rule). This is why the compliance policy is nowhere in the final rule. 21 C.F.R. § 1100 *et. seq.* As the Ninth Circuit explained in *Takhar v. Kessler*, 76 F.3d 995 (9th Cir. 1996), which is expressly cited in the ENDS Regulations, 81 Fed. Reg. at 28,977, substantive rules generally change law or policy, but interpretive rules clarify or explain existing regulations, 76 F.3d at 1001–02. In that case, the FDCA itself made the conduct illegal, and the regulation merely explained "how the FDA will use its limited resources in enforcing existing law." *Id.* Applied here, the compliance policy is the FDA's public statement that it will temporarily withhold enforcement of certain portions of the FDCA which by statute are now fully applicable to ENDS products. The FDA's decision to do so, however, has no effect on state law requirements.

Similarly, while Defendant argues that the FDA's decision not to require AP or DA to be disclosed on labels was part of a "meticulous consideration of scientific evidence," the FDA stated in the ENDS Regulations that it has taken under advisement suggestions to impose product standards pursuant to 21 U.S.C. § 387g on newly deemed products and is considering whether or not to do so. 81 Fed. Reg. at 28,979. This matches its position in the Draft Guidance, where it states that it intends to begin the process of regulating chemicals in e-liquids, including AP and DA. Draft Guidance at 26 n.28. A state law requiring disclosure of AP and DA therefore would not conflict with the TCA or ENDS Regulations because the FDA has not yet made a decision on whether it will do the same exact thing, and even if the FDA had expressly chosen not to require disclosure of AP and DA, Defendant has not explained how greater disclosure under state law is an obstacle to achieving any federal objective.

For the foregoing reasons, the Court DENIES Defendant's Motion to Dismiss Plaintiffs' claims based on conflict preemption.

D. Primary Jurisdiction

Defendant also moves the Court to dismiss this case pursuant to the primary jurisdiction doctrine. Mot. at 19. The primary jurisdiction doctrine is not a jurisdictional doctrine but rather a prudential one that permits a court in limited circumstances to "refer" an issue of first impression or a particularly complicated issue that Congress has committed to an agency, when "protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114–15 n.9 (9th Cir. 2008) (citation and internal quotation marks and omitted) (noting that referral is not the best word because most statutes do not require

an agency to rule, and the court merely stays or dismisses the action while the parties independently pursue administrative remedies).

The Ninth Circuit has held primary jurisdiction should be used to allocate initial decision making responsibility between agencies and courts when jurisdictional overlap creates the potential for conflict, *Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir. 2002), but it is not a doctrine to be invoked merely when a court is presented with an issue that may require some expert advice. *Id.*

Syntek identified four factors relevant to the doctrine of primary jurisdiction: "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Id.* at 775, 781. The Ninth Circuit has also held that court "must also consider whether invoking primary jurisdiction would needlessly delay the resolution of claims," because "efficiency is the deciding factor in whether to invoke primary jurisdiction." *Astiana*, 783 F.3d at 760 (citation omitted).

Defendant's invocation of primary jurisdiction in this case is novel because the FDA recently finalized the ENDS Regulations and because Defendant has not stated it intends to specifically ask the agency for a decision on any of the disputed issues. Instead, Defendant is asking the Court to dismiss this action in case someone submits a premarket tobacco application PMTA for a product which contains AP or DA and the FDA approves the application, presumably without requiring the disclosure of AP or DA. Mot. at 21. Defendant then asserts that such approval would "eviscerate" Plaintiffs' claims. *Id.*

The Court rejects this argument for a number of reasons. First, Defendant never states it intends to bring the issue in front of the FDA or even fill out a PMTA for its own products, 81 Fed. Reg. at 28,977, 29,011 (noting that entities that fill out a substantial equivalence exemption will likely have to provide less scientific data than a PMTA); thus, Defendant cannot state with any certainty that a PMTA will ever be filed with the FDA for a product that contains AP or DA. Defendant also fails to explain how Plaintiffs would be able to bring this issue before the FDA on their own. Second, Defendant argues that Plaintiffs would have to wait 24 months for the premarket review process to finish, but Plaintiffs would actually have to wait up to 36 months for the compliance period for PMTAs to end. 81 Fed. Reg. at 29,011. This means Defendant is asking the Court to stay or dismiss this action for up to three years based on the possibility that someone will file a PMTA with AP or DA, and it assumes the FDA will complete its review on time, and that the FDA will even rule on the issue at all. This means that Plaintiff Hirtzel, who

purchased Defendant's products in 2013, SAC ¶ 29, could wait until 2019 to refile his complaint.

Another problem with applying the doctrine in this case is Defendant has articulated multiple theories on what "issue" it would like the FDA to resolve with regards to AP and DA. In the Motion, Defendant identifies the issue within the FDA's special competence as whether constituents such as AP and DA are healthy. Mot. at 21. However, in its Reply, Defendant adds the issue of whether manufacturers should be required to disclose they use chemicals such as AP and DA, and if so, "the content and form of such disclosures" because these issues "clearly affect the entire industry." Reply at 20. Regardless of which issue Defendant chooses to argue, its argument is fatally flawed because it ignores the plain statutory text of 21 U.S.C. § 387p. To the extent Defendant contends the FDA has primary jurisdiction over the health issues raised by AP and DA, it does not explain why Congress preserved and saved the authority of the states to prohibit the sale of products entirely, *id.* § 387p(a)(1), and expressly permitted state product liability suits that could presumably include claims based on AP and DA, *id.* § 387p(b). If Defendant believes the disclosure issue should be resolved by the FDA, it ignores that aside from the preservation provision, *id.* § 387p(a), Congress saved the authority of states to require information reporting and regulate the advertising and promotion of tobacco products. *Id.* § 387p(a)(2)(B). In addition, the TCA does not preempt state requirements that are identical to or less stringent than its own. *Id.* § 387p(a)(2)(A).

Based on the above, the Court concludes that the primary jurisdiction doctrine is not appropriate here. The Motion to Dismiss on this ground is therefore DENIED.

V. Disposition

For the foregoing reasons, Defendant's Motion to Dismiss is GRANTED IN PART. Defendant's Motion to Dismiss is GRANTED only as it relates to false or misleading statements on the label, its packaging, and inserts that are in addition to or different from the federal standard. In all other respects, including any claims related to content from Defendant's website, the claim is DENIED.

The Clerk shall serve this minute order on the parties.